Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009

Message Text

UNCLASSIFIED

PAGE 01 STATE 027365
ORIGIN HEW-06

INFO OCT-01 ARA-10 ISO-00 OES-06 /023 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/OIH: BROYSTER
ARA/AND:RSDRISCOLL(INFO)
----------080711Z 091412 /21
R 072226Z FEB 77
FM SECSTATE WASHDC
TO AMEMBASSY SANTIAGO

UNCLAS STATE 027365

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, CI

SUBJECT: PYROGENIC BIOLOGICAL (RECALL B-002-7)

1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT NORMAL SERUM ALBUMIN (HUMAN) 25 PERCENT, 20 ML VIAL PACKAGED IN A SMALL BLUE AND WHITE CARDBOARD BOX WITH IN-SERT. THE 20 ML VIAL LABEL READS IN PART, "NORMAL SERUM ALBUMIN (HUMAN)", USP, SALT POOR BUMINATE R 25 PERCENT XXX TRAVENOL LABORATORIES, INC., COSTA MESA, CALIFORNIA 92626, USA XXX". THE INSERT READS IN PART, "XXX ACTION - THIS SOLUTION IS OSMOTICALLY EQUIVALENT TO APPROXIMATELY 5 TIMES ITS VOLUME OF CITRATED PLASMA XXX". THE BOX IS LABELED IN PART "XXX 20 ML LIST NUMBER 060-010 NDC 0944-0490-01 XXX".

LOT NUMBER INVOLVED: 0490C0 10BA IS THE LOT BEING RECALLED. EXPLANATION OF THE CODE AS FOLLOWS: 0490 IS PRODUCT TYPE; C IS COLORADO BOULEVARD, LOS ANGELES, CALIFORNIA PLANT 1976; B IS SECOND FILLING; A IS FIRST PACKAGING. THE LOT IDENT-
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IFICATION IS STAMPED ON THE LABEL.

MANUFACTURER:

HYLAND DIVISION TRAVENOL LABS
4501 COLORADO BOULEVARD
LOS ANGELES, CALIFORNIA 90039

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RECALLING FIRM:

HYLAND, DIVISION TRAVENOL LABS
3300 HYLAND AVENUE
COSTA MESA, CALIFORNIA 92626

2. REASON FOR RECALL:

PRIOR TO DISTRIBUTION BY HYLAND DIVISION TRAVENOL LABORATORIES, INC. THIS MATERIAL WAS PYROGEN TESTED AND FOUND TO BE NON-PYROGENIC. THE LOT WAS SUBSEQUENTLY RELEASED BY THE BUREAU OF BIOLOGICS, FOOD AND DRUG ADMINISTRATION. THE CANADIAN BUREAU OF BIOLOGICS, HEALTH PROTECTION BRANCH FOUND THIS LOT TO BE PYROGENIC WHEN TESTED BY THE CANADIAN AGENCY IN RABBITS. THERE HAVE BEEN NO DEATHS OR INJURIES ASSOCIATED WITH THIS PRODUCT.

3. POST IS REQUESTED TO CONTACT FOREIGN CONSIGNEE TO DETERMINE IF CONSIGNEE HAS RECEIVED RECALL LETTER FROM FIRM DATED 22 NOVEMBER 1976. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING THIS RECALL SHOULD BE DIRECTED TO THE FIRM. FIRM INDICATES REPLACEMENT MATERIAL OF ANOTHER LOT WILL BE SENT AT NO CHARGE.

4. FOREIGN CONSIGNEE AS FOLLOWS:

DR. A. A. FORADORI
NUCLEAR MEDICINE LABS
UNCLASSIFIED

CLIN. HOSP., P O BOX 1140
SANTIAGO, CHILE
VANCE

NNN

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: BIOLOGY, MEDICAL RESEARCH
Control Number: n/a
Copy: SINGLE
Sent Date: 07-Feb-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE027365
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770044-0295
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t19770265/aaaacfvh.tel
Line Count: 100
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: fb734cca-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 18-Oct-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 3388058
Secure: OPEN
Status: NATIVE
Subject: PYROGENIC BIOLOGICAL (RECALL B-002-7)
TAGS: OGEN, ETRD, TBIO, CI
To: SANTIAGO
Type: TE
vdkvgwkey: odbc://SAS/SAS.dbo.SAS_Docs/fb734cca-c288-dd11-92da-001cc4696bcc
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